

# Exhibit B

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING,  
SALES PRACTICES, AND PRODUCTS  
LIABILITY LITIGATION**

**MDL No. 16-2738 (FLW-  
LHG)**

***THIS DOCUMENT RELATES TO ALL  
CASES***

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**PLAINTIFF STEERING COMMITTEE'S  
GLOSSARY OF TERMS RELEVANT TO THE COURT'S  
CONSIDERATION OF THE PARTIES' *DAUBERT* BRIEFS**

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Respectfully submitted,

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---- A ----

**Amphiboles** - group of minerals that constitute asbestos when in a fibrous or asbestiform habit, including actinolite, amosite, anthophyllite, crocidolite, and tremolite.

**Asbestos** – Asbestos is the generic designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series. These include the serpentine mineral chrysotile and the five amphibole minerals – actinolite, amosite, anthophyllite, crocidolite, and tremolite.

**Asbestiform or Fibrous talc** – talc which is grown in an asbestiform habit. To clarify the terminology regarding asbestos and fibrous or asbestiform talc, IARC (2010) stated that “[t]he term ‘asbestiform fibre’ has been mistaken as a synonym for ‘asbestos fibre’ when it should be understood to mean any mineral, including talc, when it grows in an asbestiform habit.” IARC (2010) at 39. IARC readdressed the issue of carcinogenicity as well: “The present Working Group also decided to expand the name of the Group-1 agent from ‘talc containing asbestiform fibres’ to ‘talc containing asbestos or other asbestiform fibres.’” IARC (2010) at 39. IARC (2012) confirmed that “the conclusions reached...about asbestos and its carcinogenic risks apply to these six types of fibres [chrysotile, actinolite, amosite, anthophyllite, crocidolite, and tremolite] wherever they are found, and that includes *talc containing asbestiform fibres*.” IARC (2012) at 219 (emphasis added). It further differentiated the types of talc, indicating that “[t]alc may also form true mineral fibres that are asbestiform in habit.” IARC (2012) at 230.

**Association** - the degree of statistical relationship between two or more events or variables. Events are said to be associated when they occur more or less frequently together than one would expect by chance. Association does not necessarily imply a causal relationship. Events are said not to have an association when the agent (or independent variable) has no apparent effect on the incidence of a disease (the dependent variable). This corresponds to a relative risk of 1.0. A negative association means that the events occur less frequently together than one would expect by chance, thereby implying a preventive or protective role for the agent (e.g., a vaccine).

---- B ----

**Beneficiation** - process that results in purification of ore by removing minerals to result in a higher grade product.

**Bioaccessible** - a substance that is potentially available for absorption.

**Bioavailable** - the rate and extent to which a chemical or chemical breakdown product enters the general circulation, thereby permitting access to the site of toxic action.

**Bias** - refers to a systematic distortion in study findings, resulting from the way the study was designed or the way the data are collected. Specific examples of types of bias will be discussed below as they pertain to talc and ovarian cancer.

**Biological plausibility** – consideration of existing knowledge about human biology and disease pathology to provide a judgment about the plausibility that an agent causes a disease.

**Bradford Hill** – issues to consider when performing a cause and effect assessment. Such assessments are routinely performed by scientists by considering some basic characteristics: strength of association, consistency, specificity, temporality, biologic plausibility, dose-response, coherence, experiment, analogy. Dr. Hill said *“None of my nine viewpoints can bring indisputable evidence for or against the cause and effect hypothesis and none can be required as a sine qua non. What they can do, with greater or less strength, is help us to make up our minds on the fundamental question – is there any other way of explaining the set of facts before use, is there any other answer equally, or more likely than cause and effect?”*

**Bursal sac** - fluid-filled sac or saclike cavity situated in places in tissues where friction would otherwise occur. Unlike humans, the ovaries of rats and mice are completely covered by a bursal sac, making direct access to ovarian tissue unlikely when exposure is assumed to be due to vaginal penetration and migration to the ovaries.

---- C ----

**Cancer Prevention Coalition** - founded in 1994, it is a nationwide coalition of leading independent experts in cancer prevention and public health that advocate on issues in order to prevent cancer. They partner with citizen activists and representatives of organized labor, public interest, environmental, and women's health groups.

**Cancer promoter** – a tumor promoter is generally defined as a chemical, a complex of chemicals, or a biological agent that promotes a later stage of carcinogenesis, called tumor promotion, by altering expression of the genetic information, rather than altering the structure of DNA.

**Carcinogenesis** - production of cancer.

**Case-control epidemiological study** - epidemiologic method that begins by identifying people with a disease or condition of interest and compares their past history of exposure to identified or suspected risk factors with the past history of similar exposures among those who resemble the cases but do not have the disease or condition of interest.

**Case report** - a food or herbal additive that has not been formally evaluated by the U.S. Food and Drug Administration (FDA) but, on the basis of long experience in its use or the testimony of experts, is thought not to cause harm.

**“Cause” of disease** - a cause of a disease is any agent or characteristic (environmental, lifestyle or genetic) that increases the probability of getting the disease or it may simply advance or hasten the onset of the disease. It may act alone or it may act in concert with other factors over a lifetime to cause the disease. It may act immediately (e.g., cyanide as a cause of poisoning; lack of seat belt use as a cause of car accident mortality) or it may take many years for the effect to become manifest (e.g., lack of physical activity as a cause of obesity). There may be many different causes for the same disease.

**Chronic inflammation** - prolonged and persistent inflammation marked chiefly by new connective tissue formation and the presence of macrophages and lymphocytes; it may be a continuation of an acute form or a prolonged low-grade form.

**CIR** - the CIR, or Cosmetic Ingredient Review, is an expert panel process that is administered through the PCPC. It is an industry-funded process that typically is undertaken based on some impetus for review that is initiated within government, industry or the public. It evaluates individual chemical compounds as they are used in cosmetic products and produces reports of the panel’s findings. It was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. Although funded by the PCPC, the CIR and the review process are supposed to be independent from the Council and the cosmetics industry.

**Cleavage** - refers to the preferential breakage of crystals along certain planes of structural weakness. Such planes of weakness are called cleavage planes.

**Cohort epidemiological study** - a study that starts with the identification of persons with a disease (or other outcome variable) and a suitable control (comparison, reference) group of persons without the disease. Such a study is often referred to as retrospective because it starts after the onset of disease and looks back to the postulated causal factors.

**Confidence interval** – a range of values calculated from the results of a study within which the true value is likely to fall; the width of the interval reflects random error. Thus, if a confidence level of .95 is selected for a study, 95% of similar studies would result in the true relative risk falling within the confidence interval. The width of the confidence interval provides an indication of the precision of the point estimate or relative risk found in the study; the narrower the confidence interval, the greater the confidence in the relative risk estimate found in the study. Where the confidence interval contains a relative risk of 1.0, the results of the study are not statistically significant.

**Confounder** - a factor that is both a risk factor for the disease and a factor associated with the exposure of interest. Confounding refers to a situation in which an association between an exposure and outcome is all or partly the result of a factor that affects the outcome but is unaffected by the exposure.

**Core logs** - the recorded lithology (rock types) and mineralogy of sections of cylindrical core drilled from rock or a mineral deposit.

**Cosmetic warning standard** - At 21 CFR 740.1, the standard in place for cosmetic warnings is stated as follows:

*740.1 Establishment of warning statements*

*(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.*

**CTFA/PCPC** - the Cosmetic, Toiletry and Fragrance Association (CTFA) is the original name for the trade organization now known as the Personal Care Products Council (PCPC). It is the trade organization that serves the cosmetics industry and companies such as Johnson & Johnson and Imerys have been members of both.

**Cytokine** - A general term for non-antibody proteins released by a specific type of cell as part of the body's immune response.

---- D ----

**Dose-response relationship** - a relationship in which a change in amount, intensity, or duration of exposure to an agent is associated with a change—either an increase or a decrease—in risk of disease. It is important not only to assess whether there is an association between a variable and a disease when the variable is defined in a binary (exposed vs unexposed) way, but also when the variable is defined in a quantitative or semi-quantitative way. When analyzed, the risk as a function of the degree or duration or intensity of exposure, it is referred to as a dose-response (or exposure-response) analysis.

---- E ----

**Epithelial ovarian carcinomas –**

**Serous [low-grade and high-grade]** - these tumors bear a resemblance to fallopian tube epithelium and are derived from the fallopian tube.

**Endometrioid** - these tumors bear a resemblance to the endometrium (lining of the uterine cavity) and arise from endometriosis or an endometriotic cyst.

**Clear cell** - these tumors are related to endometrioid carcinoma, but the cells contain clear cytoplasm and also arise from endometriosis.

**Seromucinous** - these tumors are composed of a variety of different cell types including serous, mucinous and endometrioid cells. They are also derived from endometriosis.

**Mucinous** - these tumors contain abundant mucin in the cytoplasm and superficially resemble tumors from the gastrointestinal tract.

**Carcinosarcoma** - a highly malignant tumor that has the appearance of both a carcinoma and a sarcoma. Recent immunohistochemical and molecular genetic studies indicate that these are essentially carcinomas that have a component that simulates a sarcoma.

**Exposure metric** - signifies a way of defining a variable for statistical analysis. The simplest metric is a binary variable: exposed or unexposed. For most exposure variables, like exposure to talc powder, there can be a very wide range of degree of exposure. And it is pertinent to create more nuanced exposure metrics that take into

account the degree of exposure that different people have experienced, metrics such as duration of exposure, intensity or frequency of exposure and even cumulative measures of exposure over long periods of time.

---- F ----

**Fibrogenic** - referring to or causing the formation of fibrous tissue.

**Foreign body giant cell** - a multi nuclear cell resulting from the fusion of macrophages that is elicited in response to a foreign body, such as a suture or, in the case of this litigation, talc.

**Froth flotation** - a beneficiation process that entails the separation of minerals by exploiting their difference in hydrophobicity (attraction to water) – the aim is to “float” the mineral of interest while contaminants settle out.

---- G ----

**Genotoxic** – damaging to the genetic code within a cell and causing mutations, which may lead to carcinogenesis.

**Granuloma** - a nodular aggregation of mononuclear inflammatory cells, generally macrophages reassembling epithelial cells (epithelioid cells), usually surrounded by a rim of lymphocytes, often with multinucleated giant cells.

**GRAS substance** - A food or herbal additive that has not been formally evaluated by the U.S. Food and Drug Administration (FDA) but, on the basis of long experience in its use or the testimony of experts, is thought not to cause harm.

---- H ----

**Habit** - description of the general external shape and form of a crystal mineral.

**Hazard assessment** - an evaluation of the environmental dangers to which a site may be subject.

**Hyperplasia** - cellular growth that is beyond what is normally seen in a particular tissue. The significance of this feature is that besides growing more rapidly, highly proliferating cells have a greater chance of undergoing a mutation leading to malignant behavior.



---- I ----

**IARC** - an acronym for the International Agency for Research on Cancer. It is part of the World Health Organization. The agency coordinates and conducts both epidemiological and laboratory research into the causes of human cancer. The agency has established a monograph program where independent panels of scientists (IARC Working Group) meet to identify carcinogenic hazards and evaluate environmental causes of cancer in humans. IARC identifies carcinogenic hazard based on qualitative assessment of data collected in animals and in humans. The IARC Working Groups classifies agents, mixtures and exposures into one of four categories. The categories are chosen based on application of scientific judgement that reflects the strength of the available evidence. The classification is based only on the strength of evidence for carcinogenicity (Hazard), not on the relative increase of cancer risk due to exposure, or on the amount of agent exposure necessary to cause cancer (risk assessment).

**IARC cancer classifications** - the four current classifications of cancer hazard applied by IARC are: 1) Group 1 (carcinogenic to humans); 2) Group 2A (probably carcinogenic to humans); 3) Group 2B (possibly carcinogenic to humans); and 4) Group 3 (not classifiable as to its carcinogenicity to humans).

**Incidence of disease** - the incidence of a disease refers to the proportion of a population who are newly diagnosed with the disease during a certain period of time. The bridge between incidence rate and prevalence rate is the average duration of the disease, or how long people live with it before they are cured or pass away. In fact, while incidence and prevalence are foundational concepts in epidemiology, it is only incidence that figures prominently in the evaluation of carcinogenicity of talc.

**Incidence rate** – the number of people in a specified population falling ill from a particular disease during a given period. More generally, the number of new events (e.g., new cases of a disease in a defined population) within a specified period of time.

**Inflammation** – complex response to injury that involves molecular mediators, immune cells, and the vascular system and that serves as a mechanism to eliminate noxious agents and damaged tissue. Inflammation can be acute (short-term), or chronic (long-term).

**Inflammatory cytokines** – cytokines are regulators of host responses to infection, immune responses, inflammation, and trauma. Some cytokines act to make disease worse (proinflammatory cytokines), whereas others serve to reduce inflammation and promote healing (anti-inflammatory cytokines).

**Irritant** - an agent that causes irritation.

**In vitro** -- within an artificial environment, such as a test tube (e.g., the cultivation of tissue in vitro).

**In vivo** -- within a living organism (e.g., the cultivation of tissue in vivo).

---- **L** ----

**Lymphatic transport** – the movement of fluid and particles throughout the body through the lymph system.

---- **M** ----

**Macrophage** - a monocyte that has left the circulation and settled and matured in a tissue.

**Mesothelial cell** - one of the flat cells of mesodermal origin that form the superficial layer of the serosal membranes lining the body cavities of the abdomen and thorax.

**Meta-analysis** - there are two distinct ways that evidence from multiple studies can be combined to derive a new overall statistical summary or synthesis of those studies, a meta-analysis and a pooled analysis. A meta-analysis uses the published results from each study and averages those results using some optimal weighting procedures. In order to implement a meta-analysis, it is necessary to find all relevant studies on a topic that have published results in a fairly standardized way. The statistical algorithms typically used to average the results from different studies also provide statistics that evaluate how heterogeneous are the results from the different studies. The interpretation of such heterogeneity statistics is not straightforward. If the results from different studies are homogeneous, it adds to the confidence in the meta-estimate. If they are heterogeneous, it may indicate that the association is really different in different populations, or that there are some methodological characteristics of the different studies that have influenced the results in different ways. Unless a significant methodological flaw can be identified that has caused the heterogeneity, the best overall estimate remains the meta-estimate.

**Mutagen** – a substance that causes physical changes in chromosomes or biochemical changes in genes.

**Mutagenesis** – the process by which agents cause changes in chromosomes and genes.

---- N ----

**Neutrophils, lymphocytes, plasma cells, histiocytes (macrophages)** - these are mononuclear cells involved in the immune response, both cell-mediated and humoral (production of antibodies by plasma cells).

**NTP** - an acronym for the National Toxicology Program. It is an interagency program established in 1978 to coordinate toxicology research and testing across the U.S. Department of Health and Human Services. The three core agencies involved are National Institute of Environmental Health Sciences (NIEHS), the Food and Drug administration (FDA) and the National Institute for Occupational Health and Safety (NIOSH). Their mission is stated to be to “work continually to strengthen the science in toxicology, improve testing methods, and provide information about potentially toxic substances to government entities, scientific and medical communities, and especially the public”. They perform cancer studies in animals based on compounds nominated for consideration. They performed the talc inhalation toxicology studies in mice and rats.

---- O ----

**Odds Ratio (OR)** - the ratio of the odds that a case (one with the disease) was exposed to the odds that a control (one without the disease) was exposed. For most purposes the odds ratio from a case-control study is quite similar to a risk ratio from a cohort study. For example, if 10% of all people exposed to a chemical develop a disease, compared with 5% of people who are not exposed, then the odds of the disease in the exposed group are  $10/90 = 1/9$ , compared with  $5/95 = 1/19$  in the unexposed group. The odds ratio is  $(1/9)/(1/19) = 19/9 = 2.1$ . An odds ratio of 1 indicates no association.

**Omentum** - a fold of peritoneum, composed mostly of fat, extending, like an apron, from the stomach to adjacent organs in the abdominal cavity.

**Ovarian Cancer** - there are five major subtypes: epithelial, germ cell, gonadal stroma~nonspecific and metastatic.

**Oxidative stress** - any of various pathological changes seen in living organisms in response to excessive levels of reactive oxygen species (free radicals) in the cellular environment.

## ---- P ----

***P* (probability), *p*-value** -- the *p*-value is the probability of getting a value of the test outcome equal to or more extreme than the result observed, given that the null hypothesis is true. The letter *p*, followed by the abbreviation “n.s.” (not significant) means that  $p > .05$  and that the association was not statistically significant at the .05 level of significance. The statement “ $p < .05$ ” means that *p* is less than 5%, and, by convention, the result is deemed statistically significant. Other significance levels can be adopted, such as .01 or .1. The lower the *p*-value, the less likely that random error would have produced the observed relative risk if the true relative risk is 1.

**Perineum** - the diamond-shaped region of the body between the pubic arch and the anus. Perineal is relating to the area of the perineum.

**Peritoneum** - the serous membrane lining the cavity of the abdomen and covering the abdominal organs.

**PLM (polarized light microscopy)** - type of microscopy where a polarizing plate converts natural light into polarized light, which is shone on a specimen. PLM is used extensively in mineralogy to identify birefringent samples such as talc and asbestos.

**Pooled analysis** - there are two distinct ways that evidence from multiple studies can be combined to derive a new overall statistical summary or synthesis of those studies, a meta-analysis and a pooled analysis. A pooled analysis is one in which the investigator gets access not only to the published results from different studies, but rather to the individual data of every person in the studies. The latter is harder to achieve because it requires high buy-in and input from the investigators of the original studies; a meta-analysis is much easier to organize. Because a pooled analysis allows for standardization in the definition of variables and statistical models, it can be a more powerful means of summarizing data than the original studies themselves.

**Power** -- the probability that a difference of a specified amount will be detected by the statistical hypothesis test, given that a difference exists. In less formal terms, power is like the strength of a magnifying lens in its capability to identify an association that truly exists.

**Prevalence of disease** - the prevalence of a disease refers to the proportion of a population who are living with the disease at any given point in time.

---- R ----

**Rate** – In an epidemiological study, the number of events, divided by the size of the population; often cross-classified by age and gender. For example, the death rate from heart disease among American men ages 55–64 in 2004 was about three per thousand. Among men ages 65–74, the rate was about seven per thousand. Among women, the rate was about half that for men. Rates adjust for differences in sizes of populations or subpopulations. Often, rates are computed per unit of time, e.g., per thousand persons per year.

**Recall bias** – systematic error resulting from differences between two groups in a study in accuracy of memory. For example, subjects who have a disease may recall exposure to an agent more frequently than subjects who do not have the disease.

**Relative Risk (RR)** - The ratio of the risk of disease or death among people exposed to an agent to the risk among the unexposed. When  $RR > 1.0$ , it indicates that exposure to the agent increases the risk of developing the disease. When  $RR < 1.0$ , it indicates that exposure to the agent prevents the disease. When  $RR = 1.0$ , it indicates that the exposure to the agent has no bearing on the risk of getting the disease.

**Risk assessment** - characterization of the potential adverse effects on human life or health or on the environment. According to the National Research Council's Committee on the Institutional Means for Assessment of Health Risk, human health risk assessment includes the following: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicological, and environmental research (hazard identification); extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure (dose–response assessment); judgments regarding the number and characteristics of persons exposed at various intensities and durations (exposure assessment); summary judgments on the existence and overall magnitude of the public-health problem; and characterization of the uncertainties inherent in the process of inferring risk (risk characterization).

**Risk of disease** - the risk of disease is a term that can refer to incidence or prevalence. The meaning should be clear from the context in which it is used. For studies of cancer, it almost always refers to incidence of disease.

**Risk factor** – something that increases the chance of developing a disease. Some examples of risk factors for cancer are age, a family history of certain cancers, use of tobacco products, being exposed to radiation or certain chemicals, infection with certain viruses or bacteria, and certain genetic changes.

**RoC process** - in 1978, the U.S. Congress amended Section 301(b)(4) of the Public Health Service Act, to require the Secretary of the Department of Health and Human Services (DHHS) to publish an annual report that contains a list of all substances that “are known to be human carcinogens or may reasonably be anticipated to be human carcinogens and to which a significant number of persons residing in the United States are exposed”.<sup>39</sup> The process of producing the list, known as the Report on Carcinogens, or RoC, results from periodic meetings and is a process managed by the NTP on behalf of DHHS.

**ROS** - Reactive Oxygen species. A type of unstable molecule that contains oxygen and that easily reacts with other molecules in a cell. A build up of reactive oxygen species in cells may cause damage to DNA, RNA, and proteins, may cause cell death, and may cause cancer.

---- S ----

**Sample size** - refers to the number of participants in the study. As a generalization, large studies produce more statistically stable and precise estimates than small studies. The stability of estimates or precision of estimates is not a simple function of the number of participants, or subjects, in a study. The precision of estimates depends, among other things, on the type of epidemiologic design. In a case-control study the main determinants are the numbers of cases and controls and the prevalence of exposure in the two groups; in a cohort study the main determinants are the numbers of participants, prevalence of exposure, and the incidence of the disease of interest over the period of follow-up in the exposed and unexposed groups. There is sometimes confusion about the notion of sample size when we compare cohort studies with case-control studies. The operational aspect of an epidemiologic study of cancer that most influences the precision of an estimate of RR is not the total number of participants; rather, it is the smaller number between the number of exposed cases of disease and the number of unexposed cases. In a typical prospective cohort study, one might need to enroll 100,000 participants in order to end up with a certain number of cases (say, 500 cases) of the disease of interest (e.g. ovarian cancer). In a case-control design one might only need to enroll around 500 cases and 1500 controls to achieve the same statistical power as would be achieved by a cohort study of 100,000.

**SEM (scanning electron microscopy)** - type of microscopy where a concentrated electron beam is scanned over the surface of a sample to produce an image.

**Serpentine** - rock comprised of one or more minerals from the serpentine group (including chrysotile).

**Sex cord stromal tumors** - several tumor types derived from the stromal component of the ovary, which is responsible for the production of steroid hormones. Accordingly, several of these tumors may secrete estrogens or androgens. The different types are not the subject of this litigation.

**Somatic mutation** - mutations occurring in different cells in the body. Often referred to as acquired mutations, these occur after birth; in other words, the individual was not born with these mutations, in contrast to germline mutations.

**Stage** - the extent to which a tumor has spread at the time of diagnosis. This is determined both by the findings at surgery and by the microscopic findings (pathologic diagnosis).

---- **T** ----

**Talc** - a flexible hydrous magnesium silicate, which may occur in a variety of forms (massive or platy, foliated and fibrous).

**Threshold** – the level above which effects will occur and below which no effects occur. See no observable effect level.

**TEM (transmission electron microscopy)** - type of microscopy where a beam of electrons is transmitted through a specimen to produce an image. TEM has a much higher resolution than light microscopy.

---- **V** ----

**Valence state** - the quality that determines the number of atoms or groups with which any single atom will unite chemically.

---- **X** ----

**XRD (X-ray Power Diffraction)** - technique where X-rays are diffracted off a specimen and the angles and intensities of the diffracted beams are used to determine the atomic structure and thus identify a crystalline material.